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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/649,811	08/28/2000	Jiangchun Xu	210121.471C11	7348

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1642	5

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/649,811	XU ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE f this communication appears n the cover she t with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Prior to setting forth the restriction requirement, it is noted that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461,198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the products are polypeptides, which differ in structure and origin to such an extent that non-coextensive searches are required, and that the polypeptides are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility. As such, the structurally different polypeptides have been restricted each from the other. Further, the polynucleotides encoding the separate polypeptides have been restricted from each other; and further, the antibodies that bind to the separate polypeptides have been restricted from each other. Additionally, for claims that recite Markush groups the encompass polypeptides, together with polynucleotides and antibodies, these inventions have been restricted into separate invention groups (see claims 17-22).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 12-15, 17-20, drawn to polypeptides, classified in class 530, subclass 300, 350, 402 or 403; or class 514, subclass 2. **Claims 17-20 are examined to the extent they read on compositions comprising polypeptides according to claims 1 and 12.**

II. Claims 4-10, 16-20, 23-28, 58-60, drawn to polynucleotides, kits comprising polynucleotides, pharmaceutical compositions comprising polynucleotides, host cells transformed with said polynucleotides, classified in class 435, subclass 325, or class 536, subclass 23.5, or class 514, subclass 44. **Claims 17-20 are examined to the extent they read on compositions comprising polynucleotides according to claims 4 and 16.**

III. Claims 11, 17-20, 54-57, drawn to antibodies, pharmaceutical compositions comprising antibodies, vaccines comprising antibodies and diagnostic kits, classified in class 530, subclass 387.1, or class 424, subclass 130.1, or class 435, subclass 975. **Claims 17-20 are examined to the extent the read on compositions comprising antibodies according to claim 11.**

IV. Claims 21 and 22, drawn to methods of inhibiting the development of cancer, comprising administration of a pharmaceutical composition or a vaccine comprising the polypeptide or fusion polypeptides of claims 1 and 12, classified in class 514, subclass 2.

V. Claims 21 and 22, drawn to methods of inhibiting the development of cancer, comprising administration of a pharmaceutical composition or a vaccine

comprising the polynucleotide of claim 4 or 16, classified in class 514, subclass 44.

VI. Claims 21 and 22, drawn to methods of inhibiting the development of cancer, comprising administration of a pharmaceutical composition or a vaccine comprising the antibody of claim 11, classified in class 424, subclass 130.1.

VII. Claims 29-31, drawn to methods of inhibiting the development of cancer, comprising the administration of an antigen presenting cell, classified in class 424, subclass 93.1, class 424, subclass 277.1, class 424, subclass 130.1, class 514, subclass 2.

VIII. Claims 32-34, drawn to methods for removing tumor cells from a biological sample, classified in class 424, subclass 93.7.

IX. Claims 35-39, drawn to methods for stimulating or expanding T-cells, classified in class 424, subclass 93.71.

X. Claims 40-47, drawn to methods for determining the presence or absence of a cancer in a patient, or methods for monitoring the progression of cancer in a patient, comprising the use of a binding agent, classified in class 435, subclass 4, or 7.1.

XI. Claims 48-53, drawn to methods for determining the presence of absence of a cancer in a patient, or methods for monitoring the progression of cancer in a patient, comprising the use of an oligonucleotide, classified in class 435 subclass 4 or 6.

For each of invention sets I-XI above, restriction to one of the following **is also** required under 35 USC 121. Therefore, election is required of one of inventions I-XI **and** one of the following inventions:

(A) if group I is selected, then a polypeptide encoded by one of the sequences recited in claim 1 is selected.

(B) if group II is selected, then a polynucleotide encoding one of the polypeptides of group I is selected.

(C) if group III is selected, then a polypeptide encoded by one of the sequence of recited in claim 1 is selected.

(D) if group IV is selected, then a polypeptide encoded by one of the sequence recited in claim 1 is selected.

(E) if group V is selected, then a polynucleotide encoding one of the polypeptides of group I is selected.

(F) if group VI is selected, then a polypetpide encoded by one of the sequences recited in claim 1 is selected.

(G) if group VII is selected, then a polypeptide encoded by one of the sequences recited in claim 29 is selected.

(H) if group VIII is selected, then a polypeptide encoded by one of the sequences recited in claim 32 is selected.

(I) if group IX is selected, then a polypeptide encoded by one of the sequences recited in claim 35 is selected.

(J) if group X is selected, then a polypeptide encoded by one of the sequences recited in claim 40 is selected.

(K) if group XI is selected, then a polypeptide encoded by one of the sequences recited in claim 48 is selected.

2. The inventions are distinct, each from the other because of the following reasons:

The individual polypeptides and polynucleotides referred to in groups (A)-(K) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different polypeptides and polynucleotides represent structurally different compounds. Therefore, where structural identity is required, such as for hybridization, or for detection of an antibody or for the production of an antibody, the different, individual polynucleotides and polypetpides have different effects.

3. The methods of Inventions IV-XI differ in the method objectives, method steps and parameters and in the reagents used. Some of the inventions require the use of polypeptide products, some require the use of polynucleotide products, some require the use of antigen presenting cell products, and some require the use of antibody products. Furthermore, some of the methods are in vivo treatment methods that differ in method steps and objectives from the in vitro methods of purification or detection of disease. Thus, Inventions IV-XI are patentably distinct inventions.

4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of invention I can be used in the purification and isolation of antisera, which is a method that is materially different from the methods of in vivo treatment of invention group IV.

Inventions II and V or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of invention II can be used in either of the methods of V or IX, which are patentably distinct methods.

Inventions III and VI or VIII or X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of invention III can be used in any one of the separate and distinct methods of groups VI, VIII or X.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Anne L. Holleran
Patent Examiner
October 1, 2003

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